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10/533,289	04/29/2005	Lars Martensson	1027651-000272	6042

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EXAMINER	
YOO, REGINA M	

ART UNIT	PAPER NUMBER
1773	

NOTIFICATION DATE	DELIVERY MODE
12/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,289	MARTENSSON ET AL.	
	Examiner	Art Unit	
	REGINA YOO	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-19 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-19 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

FINAL ACTION

Response to Amendment

The amendment filed on 9/27/2010 has been received and claims 1-4, 6-19 and 36 are pending.

Claim Objections

1. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, the claim does not further limit the parent structurally but rather appears to specify a content thereof during an intended operation, which is of no significance in determining patentability of the apparatus claim (see MPEP §2115).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4, 6-8, 12-18 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) in view of Taggart (6475435).

As to Claims 1, 3 and 36, Zelina ('915) discloses a device for sterilization in production of packages (120) prior to filling the packages (120) (wherein filling occurs in 190; see entire document, particularly Figure 8), which is adapted for sterilization with a gaseous sterilizing agent in the form of gaseous hydrogen peroxide (see entire document, particularly Abstract) kept in the gaseous phase throughout the sterilization process (see entire document, particularly p.5 [0061]), said device comprising a heating zone (170), a sterilization zone (11), a venting zone (182), and means (126, 128, 172, 174, 176, 178, 180) for controlling a flow of gaseous sterilizing agent in the sterilization zone (11) such that the gaseous sterilizing agent is both introduced into and evacuated from the sterilization zone (11) (see Figure 8), wherein the heating zone comprises means (171) for heating the packages (120) to a temperature above a dew point of the sterilizing agent used in the sterilization zone (11) (see entire document, particularly Figure 8 and p. 5 [0062]).

Zelina ('915) does not appear to specifically teach that the device for sterilization in production of packages is comprised of means for maintaining a higher positive pressure in the sterilization zone than in the heating zone and venting zone, or that the means for controlling a flow that provides/operates at such a rate that the higher positive pressure is maintained in the sterilization zone, or that the means for heating comprises means for introducing and withdrawing hot air in the heating zone.

It was well known in the art at the time of invention to means for maintaining a higher positive pressure in the sterilization zone than in the heating zone and venting zone as well as to provide such a rate that the higher positive pressure is maintained in the sterilization zone via the means for controlling flow of gaseous agent in a sterilization device for packages and to provide the means for heating comprises means for introducing and withdrawing hot air as the means for heating.

Taggart ('435) discloses a device (10) for sterilization in production of packages (12), which is adapted for sterilization with a gaseous sterilizing agent kept in the gaseous phase throughout the sterilization process (see entire document, particularly Abstract, Col. 8 lines 35-37, and Cols. 9-10), said device (10) comprising a heating zone (164), a sterilization zone (166), a venting zone (172), means (including 140, 142, 144) for maintaining a higher positive pressure in the sterilization zone (166) than in the heating zone (164) and venting zone (172) (see Col. 9 lines 42-46), and means (550 as well as various components such as flow sensors, pressure and temperatures sensors and related pumps,

valves, etc. – intrinsically disclosed in the reference) for controlling flow of a gaseous agent in the sterilization zone (166) such that the gaseous agent is introduced into the sterilization zone (166) at a rate that the higher positive pressure is maintained in the sterilization zone (166) (see Col. 5 lines 16-18 and Col. 14 line 43 to Col. 16 line 15, specifically Col. 15 lines 43-48), wherein the heating zone (164) comprises means for heating the packages to a temperature above a dew point of the sterilizing agent used in the sterilization zone (see entire document, particularly Col. 10 lines 3-7) such that packages (12) are heated by means for introducing (via 148, 150, 152) and withdrawing (via 153) hot sterile air in the heating zone (164) (see Figures 3 and 15 and Col. 10 lines 3-7, 12-15 and 32-45), in order to provide a highly sterile zone to ensure that no contaminant will enter during the package (12) assembling/filling process (see Col. 9 lines 39-41) and to heat the packages so as to activate and dry sterilant from the packages (see Col. 10 lines 32-45).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide a means for maintaining a higher positive pressure in the sterilization zone than in the heating zone and venting zone as well as controlling means to provide a rate for the gaseous agent to maintain the higher positive pressure in the sterilization zone and to provide means for introducing and withdrawing hot sterile air in the heating zone in the device of Zelina in order to ensure that no contaminant will be present in the heating and sterilization zones as well as to activate/dry sterilant on the packages as shown by Taggart.

As to Claim 2, Zelina ('915) discloses that said zones are separated from each other by partitionings having openings for the passage of packages (see Figures 1 and 8).

As to Claim 4, Zelina ('915) discloses that the device is adapted to sterilize packages (120) before filling of the packages (120), said packages (120) having an open end (123, 134) and a closed end (132) (see entire document, particularly Figures 1 and 8).

As to Claim 6, Zelina ('915) discloses that the venting zone (182) comprises means (183, 184) for venting away the sterilizing agent used in the sterilization zone (11) from the packages (120) after sterilization (see entire document, particularly Figure 8 and p. 6 [0064]).

As to Claim 7, Zelina ('915) discloses that in the sterilization zone (11), the gaseous sterilizing agent flows essentially in a direction from the open end (123, 134) of the packages (120) towards the closed end (132) of the packages (120) (see entire document, particularly Figure 8, p. 5 [0063] and p. 6 [0067]).

As to Claim 8, while Zelina ('915) does not appear to specifically teach in the embodiment shown in Figure 8 that the means for controlling the flow of gaseous sterilizing agent are arranged to introduce the gaseous sterilizing agent in a top portion of the sterilization zone (11) and to evacuate the gaseous

sterilizing agent in a bottom portion of the sterilization zone (11), maintaining a flow of gaseous sterilizing agent essentially from top to bottom, Zelina ('915) discloses an alternate embodiment wherein the means (14, 10, 200) for controlling the flow of gaseous sterilizing agent are arranged to introduce the gaseous sterilizing agent in a top portion of the sterilization zone (11) and to evacuate the gaseous sterilizing agent in a bottom portion of the sterilization zone (11), maintaining a flow of gaseous sterilizing agent essentially from top to bottom (see Figure 11).

Thus, it would have been well within the purview of one of ordinary skill in this art at the time of invention to provide the configuration of means for flowing the sterilizing agent shown in Figure 11 to the embodiment disclosed in Figure 8 as a known alternate configuration to supply the sterilizing agent. Only the expected results would be attained.

As to Claim 12, while Zelina ('915) does not appear to specifically teach in the embodiment shown in Figure 8 that the device is further comprises a package heating temperature sensor for sensing the temperature of the packages entering the heating zone, Zelina ('915) teaches that the avoidance of condensation of the hydrogen peroxide vapor on the packages is important (see p. 5 [0061]) and provides means to ensure that the temperature of the packages, through heating in the heating zone (170) prior to entering the sterilization zone (11), is at a sufficient temperature that the surfaces of the packages are at or above the temperature of the sterilization zone when the packages enter the

sterilization zone, as well as while residing in the sterilization zone (see Figure 11), so as to avoid condensation occurring on the surface of the packages (see p. 5 [0059] and [0062]). Zelina ('915) further teaches that the temperature of individual package is measured and this information fed to the control system so as to modify the operation parameters of various components within the device (see p. 5 [0059]).

Thus, it would have been well within the purview of one of ordinary skill in this art at the time of invention to also provide a temperature sensor at the entry to the heating zone in the device of Zelina in order to sense the temperature of packages entering the heating zone so that the operation of heating means in the heating zone is adjusted for further/optimized control according to initial package temperature to ensure that appropriate package temperature for sterilization will be achieved within the residence time allotted for the operation/processing in the heating zone. Only the expected results would be attained.

As to Claim 13, Zelina ('915) discloses that the device is further comprised of an entry temperature sensor for sensing the temperature of the packages (120) before entering the sterilization zone (11) (see p. 5 [0059] where it is deemed that the temperature of individual package is measured before the entry into the sterilization zone so that there is sufficient notice by control system to modify the operation of the vaporizer and/or residence time of the packages in the sterilization).

As to Claim 14, Zelina ('915) discloses that the device is further comprised of a feedback circuit (see p. 5 [0057]-[0059] and [0061]) for controlling the heating in the sterilization zone (11). Zelina ('915) also teach that the temperature of individual incoming packages is also measured and monitored to ensure that the condensation does not occur by using the feedback circuit to change various operating components/parameters (see p. 5 [0059]). It is deemed that this feedback circuit is capable of controlling the heating (171) in the heating zone (170) based on the temperature of the packages (120) being measured.

As to Claim 15, Zelina ('915) discloses that the device is further comprised of a condensation detector (152, 153) for detecting condensation in the sterilization zone (11) (see entire document, particularly p.5 [0057]-[0061] where a dew point or humidity sensor is a condensation detector).

As to Claim 16, the device of Zelina ('915) is fully capable of sterilizing itself internally when the device is operated without the packages (120).

Taggart ('435) also discloses that the device (10) is adapted to sterilize itself internally (see Col. 16 lines 16-36).

As to Claim 17, Zelina ('915) discloses that the device is comprised means (171) for heating the interior of the device (see Figure 8).

As to Claim 18, Zelina ('915) discloses that the device is comprised of a unit (10) for production of the gaseous sterilizing agent (see Figure 8 and p. 5 [0060]).

Thus, Claims 1-4, 6-8, 12-18 and 36 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915) and Taggart ('435).

5. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) and Taggart (5475435) as applied to claim 4 above, and further in view of Fotti (4992247).

Zelina ('915) and Taggart ('435) are relied upon for disclosure described in the rejection of claim 4 under 35 U.S.C. 103(a).

Zelina ('915) does not appear to specifically teach that the device is further comprised of means for controlling a venting air flow in the venting zone, such that the venting air flows essentially in a direction from the open end of the packages towards the closed end of the packages nor that the means for controlling the flow of venting air are arranged to introduce the venting air in a top portion of the venting zone and to evacuate the venting air in a bottom portion of the venting zone, maintaining a flow of venting air essentially from top to bottom.

It was known in the art at the time of invention to provide a device for sterilization in production of packages using gaseous sterilizing agent with means for controlling a venting air flow in the venting zone, such that the venting air

flows essentially in a direction from the open end of the packages towards the closed end of the packages where the means for controlling the flow of venting air are arranged to introduce the venting air in a top portion of the venting zone and to evacuate the venting air in a bottom portion of the venting zone, maintaining a flow of venting air essentially from top to bottom.

Fotti ('247) discloses that a device (10) for sterilization in production of packages using gaseous sterilizing agent is further comprised of means (48, 54) for controlling a venting air flow in the venting zone (52), such that the venting air flows essentially in a direction from the open end of the packages (38) towards the closed end of the packages (38) (see entire document, particularly Figure 1 and Col. 3 lines 12-20), wherein means (48, 54) for controlling the flow of venting air are arranged to introduce the venting air in a top portion (48) of the venting zone (52) and to evacuate the venting air in a bottom portion (62, 64) of the venting zone (52), maintaining a flow of venting air essentially from top to bottom (see Figure 1) in order to remove a condensate mixture from the surface of packages (see entire document, particularly Col. 3 lines 12-15).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide means for controlling a venting air flow in the venting zone, such that the venting air flows essentially in a direction from the open end of the packages towards the closed end of the packages in the device of Zelina in order to remove the sterilizing agent from the packages as shown by Fotti.

Thus, Claims 9-10 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915), Taggart ('435) and Fotti ('247).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) and Taggart (5475435) as applied to claim 4 above, and further in view of Hanley (6565802).

Zelina ('915) and Taggart ('435) are relied upon for disclosure described in the rejection of claim 4 under 35 U.S.C. 103(a).

While Zelina ('915) discloses a device for sterilization with temperature sensors in the device, Zelina ('915) does not appear to specifically teach that the device is further comprised of an ambient temperature sensor for sensing the ambient temperature outside the device.

It was well known in the art at the time of invention to provide a temperature sensor that is located outside a device for sterilization for sensing the ambient temperature. Hanley ('802) exemplifies a sterilization device (10) comprised of a temperature sensor (145) located outside the device (10) (see Figures 1-2) in order to measure the ambient temperature of the outside environment and to provide an indication of the air temperature being delivered to within the device so that the operation of the device will be adjusted accordingly (see entire document, particularly Col. 11 lines 2-16).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide an ambient temperature sensor outside the device of Zelina

in order to measure the ambient temperature to provide an indication of temperature of the material (such as air or articles that are in equilibrium with the ambient atmosphere) being delivered into the device so as to adjust the operating parameters accordingly for optimized operation of the device as exemplified by Hanley.

Thus, Claim 11 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915), Taggart ('435) and Hanley ('802).

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zelina (20020159915) and Taggart (5475435) as applied to claim 1 above, and further in view of Catelli (5848515).

Zelina ('915) and Taggart ('435) are relied upon for disclosure described in the rejection of claim 1 under 35 U.S.C. 103(a).

While Zelina ('915) discloses that the device is further comprised of a filling zone (190) (see Figure 8), Zelina ('915) does not appear to specifically teach that the filling zone is comprised of means for maintaining a higher pressure than in the venting zone.

It was well known in the art at the time of invention to provide a higher pressure in the filling zone of a bottling device that also employees sterilization zone and a venting zone. Catelli ('515) exemplifies a device (1) comprised of a sterilization zone (10a), a venting zone (20) and a filling zone (30), as well as means (13, 14) for maintaining a higher pressure in the sterilization zone (10a)

and in filling zone (30) in order to keep each of the zones sterile (see entire document, particularly Col. 3 lines 13-17 and Col. 4 lines 64-67, where these means are independently controllable as to adjust the pressure within each zone and thus, is able to produce a higher pressure in the sterilization zone and filling zone compared to the venting zone).

It would have been obvious to one of ordinary skill in this art at the time of invention to provide the means to maintaining a higher pressure in the filling zone than in the venting zone of Zelina in order to keep the filling zone sterile so that the final product will not be contaminated as exemplified by Catelli.

Thus, Claim 19 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Zelina ('915), Taggart ('435) and Catelli ('515).

Response to Arguments

8. Applicant's arguments filed 9/27/2010 have been fully considered but they are not persuasive.

Specifically, as to Applicant's argument in page 7 of Remarks that "an ordinarily skilled artisan would seek to avoid seepage of hydrogen peroxide gas into Zelina's heating chamber 170 in order to avoid the problem of condensation of the hydrogen peroxide on the containers[; t]hus, an ordinarily skilled artisan would not have included means for maintaining a higher positive pressure in the decontamination tunnel 11 than in the heating chamber 170 in Zelina", Examiner would note this is an argument against the references individually, wherein one

cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, it is noted that Taggart discloses means for maintaining a higher pressure in the sterilization zone than in the heating zone as pointed out in the rejection of claim 1 above. Moreover, Examiner would note that as the heating zone of Zelina would be at a temperature at or above the temperature of sterilization zone in order to heat the packages to a temperature of the sterilization zone so as to avoid condensation of the sterilant in Zelina (see p. 5 [0062]), the seepage of hydrogen peroxide gas into Zelina's heating chamber 170 would not cause the problem of condensation of the hydrogen peroxide on the containers since the heating means would heat and keep the surfaces of the packages to a high enough temperature to eliminate condensation (if any) from the packages as disclosed by Zelina. In addition, as Taggart also teaches use of hot sterile air in the heating zone for drying of sterilant in the heating zone, seepage of hydrogen peroxide gas into the heating zone would not cause a problem of condensation of hydrogen peroxide and would keep the hydrogen peroxide in gaseous phase.

As to Applicant's argument in p. 8 of Remarks that Zelina does not teach means for heating that is comprised of means for introducing and withdrawing hot air in the heating zone, Examiner would note this is an argument against the references individually, wherein one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of

references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, it is noted that Taggart discloses means for introducing and withdrawing hot air in the heating zone as indicated above in the rejection of claim 1.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA YOO whose telephone number is

(571)272-6690. The examiner can normally be reached on Monday-Friday, 10:00 am - 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RY

/Sean E Conley/
Primary Examiner, Art Unit 1773